FEB 17 2006

510(K) Summary
For Brennen Medical, Inc.'s
Silver Glucan Wound Dressing

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Date Prepared: January 27, 2006

1. **Submitter**

Brennen Medical, Inc.
1290 Hammond Road
St. Paul, MN 55110

Kenneth Herland
V.P. Regulatory Affairs and Q.A.
651-429-7413

2. **Device Name**

Proprietary Name:	Silver Glucan Wound Dressing (TBD)
Common Name:	Dressing
Classification Name:	Dressing
Regulatory Class:	Unclassified

3. **Intented Use**

Silver Glucan Wound Dressing is an effective barrier to bacterial and candida penetration. The dressing may be use for partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, donor sites, and surgical wounds. Silver Glucan dressings may be used over partial thickness wounds, debrided wounds, and as a temporary covering for full thickness and grafted wounds.

4. **Device Description**

Silver Glucan dressing consists of a nylon mesh coated with silver and oat glucan. The glucan facilitates the placement of the mesh and the silver protects the wound site from bacterial and yeast contamination.

The sterile, single use dressing will be sold in a variety of sizes ranging from 4" x 4" to 16" x 16" and rolls of 4" x 48".

5. **Predicate Device Comparision**

Brennen Medical, Inc. believes the Silver Glucan to be substantially equivalent in design, materials, function, and intended use as Acticoat Silver Coated Wound Dressing, a wound dressing that is in commercial distribution and is presently marketed by Westaim Medical (now under the name of Smith-Nephew) and previously reviewed by ODE under 510(k) K955453; and Silverlon Contact Wound Dressing reviewed on K981299. Both were found substantially equivalent.

Also, the following predicate device(s) contain silver or glucan and have been reviewed by ODE and found substantially equivalent

The predicate devices are: 1. Acticoat Silver Coated Dressing (K983833, K992221, K000051, K001519 and K002466); 2. Brennen Medical, Inc. Glucan II Wound Dressing (K964241).

The predicate devices are all sterile, single use coverings for wounds. Each of the silver predicate devices, as well as this new device, employ silver metal on a support material.

The support matrix varies for each of the products. Acticoat silver coated dressing is a 3-ply gauze wound dressing consisting of an absorbent rayon/polyester core and an upper and lower layer of silver-coated high density polyethylene mesh designed to be a barrier against microbial infections of a wound. Silverlon and Silver Glucan are composed of a polymeric material (nylon). While the support matrixes vary for each product the role it provides is the same; to provide a physical barrier to the wound and provide a substrate for Ag.

The differences between the new Silver Glucan device and its predicate devices are minor and raise no new questions of safety or effectiveness. All of the products have the same intended use and are sterile and for single use.

6. Biocompatibility

The Silver Glucan Wound Dressing was subjected to the following performance tests:

- Biocompatability studies (including skin irritation, sensitization, and cytotoxicity)
- Animal Wound Healing Study
- Silver dissolution
- Tensile strength
- Barrier efficacy
- Zone of inhibition
- Stability testing

In all instances, the Silver Glucan Wound Dressing is both effective for its intended use and functions in a substantially equivalent manner to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

Mr. Kenneth B. Herland
Vice President
Regulatory Affairs and Quality Assurance
Brennen Medical, Inc.
1290 Hammond Road
Saint Paul, Minnesota 55110

Re: K050086
Trade/Device Name: Brennen Medical Silver Glucan Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 6, 2006
Received: January 9, 2006

Dear Mr. Herland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable. the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K-050086

Device Name: **Brennen Medical Silver Glucan Wound Dressing**

Indications for Use

Silver Glucan Wound Dressing is an effective barrier to bacterial and candida penetration. The dressing may be used for partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, donor sites, and surgical wounds. Silver Glucan dressings may be used over partial thickness wounds, debrided wounds, and as a temporary covering for full thickness and grafted wounds.

Prescription Use X OR Over the Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050086